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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/974,584	CECH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-127* is/are pending in the application.

4a) Of the above claim(s) *127* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/9/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on October 8, 2004 has been entered.

Claims 119-127 are pending. Claim 127 is withdrawn from consideration as being drawn to a non-elected invention.

THE FOLLOWING INCLUDE MODIFIED AND NEW GROUNDS OF REJECTION IN VIEW OF APPLICANTS AMENDMENTS TO THE CLAIMS:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 121-126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

A. The specification as originally filed does not provide basis for the concepts set forth claims 123-126 of: defining structure c) as limited to SEQ ID NO: 478 (claim 123); defining structure e) as limited to SEQ ID NO: 370 (claim 124); defining structure e) as limited to SEQ ID NO: 479 (claim 125); or for a polynucleotide that encodes a telomerase containing any 10 amino acids of SEQ ID NO: 123 in place of or in addition to the amino acids set forth in claim 119 (claim 126). The specification as originally filed discloses the concept of "isolated naturally occurring and recombinant TRT proteins comprising one or more of the motifs illustrated in Figures 55 and 57." The specification provides an example of the motifs that may be included in said telomerase. However, the specification does not specifically teach that structure b) may be SEQ ID NO: 478, structure d) may be SEQ ID NO: 370 and structure e) may be SEQ ID NO: 479.

Additionally, the structures defined in claim 119 include additional elements that are not present in the structures of claims 122-125 and/or exclude elements that are present in the structures of claims 122-125. For instance, claim 119 defines structure b) as X-Arg-X-Ile-X, whereas claim 123 defines structure b) as Arg-X-Ile-Pro-Lys. Thereby in claim 123, structure b) is missing the first amino acid and has an additional terminal amino acid. Accordingly, the specification as originally filed does not provide basis for polynucleotides encoding proteins having the specific combination of structures set forth in claims 122-125.

Furthermore, with respect to claim 126, the specification exemplifies a partial cDNA TRT clone encoding a protein having the amino acid sequence of SEQ ID NO: 123. However, the specification does not provide support for the claimed genus of a

polynucleotide encoding any TRT comprising any 10 mer amino acid fragment of SEQ ID NO: 118 present in addition to any one of structures a-f as defined in claim 119.

RESPONSE TO ARGUMENTS:

In the response of August 9, 2004, Applicants argue that since the individual structures are discussed within the specification, that Applicants are entitled to recite any combination of these elements "that read on the embodiment of most commercial interest."

Applicants arguments have been fully considered but are not persuasive to overcome the present grounds of rejection. The disclosure of an individual element in the specification does not provide basis for a genus of compounds which contain each of these elements together with other elements. The disclosure of SEQ ID NO :118, 139, 143, 144, 146, 147 and 16/17 alone or within a specific nucleotide sequence does not provide basis for the broader concept of a genus of nucleic acids having 60% identity to SEQ ID NO: 118 and comprising SEQ ID NO: 139, 143, 144, 146, 147, and 16/17. As previously discussed, Figure 55 lists a number of sequence motifs. However, this figure does not describe specific TRT nucleic acids defined in terms of comprising the sequences set forth in claim 119 wherein the sequences are further defined such that structure b) may be SEQ ID NO: 478, structure d) may be SEQ ID NO: 370 and structure e) may be SEQ ID NO: 479. The teaching of particular motifs consisting of SEQ ID NO: 478, 370 and 479 does not provide basis for the claimed genus of nucleic acids. Further, while page 46 of the specification refers to peptide immunogens that may be of a length of about 10 amino acids and page 16 refers to

antibodies that bind to a portion of a TRT peptide, the specification does not provide basis for the claimed genus of a polynucleotides encoding any TRT comprising any 10 mer amino acid fragment of SEQ ID NO: 118 present in addition to any one of structures a-f as defined in claim 119. Additionally, claims 123-125 have been amended to recite that "structure b is," "structure d) is," and "structure e) is." However, the structures set forth in claims 123-125 include amino acids that are not present in the structures recited in claim 119 and/or omit amino acids that are present in the structures recited in claim 119. The specification as originally filed does not provide support for polypeptides comprising motifs in which amino acids are added or deleted from the motifs.

B. The specification as originally filed does not provide support for the concept set forth in claim 121 in which structure f) is "joined to" SEQ ID NO: 477. The claims encompass joining SEQ ID NO: 477 to the 5' and/or 3' terminus of structure f) and joing SEQ ID NO: 477 to an internal nucleotide of structure f). The claims include both direct and indirect attachment of SEQ ID NO: 477 to structure f). While the specification as originally filed discloses that structure f) comprises SEQ ID NO: 477, the specification as originally filed does not provide basis for the broader concept of joining SEQ ID NO: 477 to structure f). For example, the specification does not provide support for nucleic acids comprising structures a), b), c), d), and e) and further comprising "SEQ ID NO:477-structure f)", or "structure f)-SEQ ID NO: 477" or "SEQ ID NO: 477-Xn-structure f)" or "structure f)-Xn-SEQ ID NO: 477."

3. Claims 119-126 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding telomerase reverse transcriptase wherein the polynucleotides comprise SEQ ID NO: 1, 51, 53, 666, 68, 417 or 419, does not reasonably provide enablement for any polynucleotide encoding a protein having telomerase catalytic activity wherein the polynucleotide comprises the motifs set forth in claim 119 and comprises "an amino acid sequence at least 60% dietetically to SEQ ID NO: 118." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the

art as well as the predictability in the art Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has not provided sufficient guidance to enable the skilled artisan to make and use the invention as it is broadly written for the following reasons:

Firstly, it is noted that the claims are drawn broadly to encompass a very large genus of polynucleotides. In particular, the claims are drawn to polynucleotides encoding a telomerase having telomerase catalytic activity wherein the polypeptide has each of the structures of e) SEQ ID NO: 16 or 17, a) SEQ ID NO: 139, b) SEQ ID NO: 143, c) SEQ ID NO: 144, d) SEQ ID NO: 146, and e) SEQ ID NO: 147. The stated sequences represent conserved motifs shared by telomerase reverse transcriptase (TRT). Each of these sequences include variable amino acid positions which may be any amino acid (X) or may be Leu or Ile (R1), Gln or Arg (R2), Phe or Tyr (R3) or Lys or His (R4), as set forth in claim 119 and in the sequence listing. The amino acids present between these motifs, the exact amino acid sequence of these motifs, the order of the motifs, the length of the amino acid sequence, and the source of the amino acid sequence are not set forth in the claims. Further, the claims are defined in terms of a polynucleotide encoding a polypeptide comprising "an amino acid sequence at least 60% identical to SEQ ID NO: 118." The claims do not require nucleic acids which encode for proteins having 60% identity over the full length of SEQ ID NO: 118. Rather the claims require nucleic acids comprising "an amino acid sequence" (i.e., any

fragment/length of amino acids) having at least 60% identity with SEQ ID NO: 118. Accordingly, the claims include genomic DNA sequences, splice variants, insertion, deletion and substitution variants having an increased or decreased level of telomerase reverse transcriptase activity, and polynucleotides encoding TRTs from any species.

The specification teaches a limited number of polynucleotides encoding telomerase reverse transcriptase proteins. Specifically, the specification teaches isolated cDNAs encoding telomerase proteins from Euplotes aediculatus, Oxytricha, Saccharomyces cerevisiae, Tetrahymena, Schizosaccharomyces pombe, mouse and human. The specification also teaches the genomic DNA encoding E. aediculatus telomerase (SEQ ID NO: 1). Further, the specification also teaches a single variant of human telomerase wherein the cDNA (SEQ ID NO: 117) encoding this polypeptide has a 182 bp deletion (see, for example, page 38 of the specification). The specification provides an alignment of TRT proteins and identifies particular regions within these protein sequences that are conserved amongst TRT proteins. The specification also teaches the general methodology for using known TRT nucleic acids to identify additional TRT nucleic acids.

However, the scope of the claims does not bear a reasonable correlation to the scope of enablement provided by the specification. The teachings in the specification of 7 specific polynucleotides does not enable one of skill in the art to obtain a representative number of polynucleotides within the broadly claimed genus without undue experimentation. The claims are inclusive of polynucleotides which are defined only in terms of the fact that they contain 6 consensus motifs and have 60% identity with

an unspecified fragment of SEQ ID NO: 118. The claims do not clearly define the overall structure of the protein encoded by the polynucleotide. The claims include splice variant and mutant polynucleotides that contain nucleotide additions, deletions and substitutions. The claims further include variants that have increased or decreased levels or altered telomerase activity as compared to wild-type sequences. However, the specification teaches only one variant human TRT which contains a 182 bp deletion. It is noted that this particular variant appears to be excluded from the claims because the claims require a polynucleotide encoding motif B' (SEQ ID NO: 146) and motif C (SEQ ID NO: 147) and these motifs are not present in the variant having a 182 bp deletion. The specification highlights the unpredictability in determining the effect of nucleotide alterations on the function of the encoded protein. In particular, the specification at page 38 states that "(a)lthough the hTRT variants lacking the 182 basepair sequence found in the pGRN121 cDNA (SEQ ID NO: 117) are unlikely to encode a fully active telomerase catalytic enzyme, they may play a role in telomerase regulation and/or have partial telomerase activity, such as telomere binding or hTR binding activity."

The specification has not identified any particular nucleotides within the TRT gene or cDNA which may be altered without effecting the functional activity of the encoded protein. Furthermore, the specification does not provide sufficient guidance to enable the skilled artisan to determine which alterations in any TRT gene can be made without altering the functional properties of the encoded protein. It is well known in the art that even a single conservative amino acid substitution can adversely affect the proper folding and biological activity of a protein if the amino acids are critical for

functional activity. While one may identify conserved amino acid regions and regions important for biological function, such information does not allow one to ascertain which amino acids will effect the tertiary structure of the protein and thereby the overall functional activity of the protein. The effect of an amino acid substitution, deletion, or addition on the activity of the claimed TRT proteins is further made unpredictable by the fact that the TRT protein does not act alone, but must be present in a complex with telomerase RNA to elicit telomerase activity.

The specification does not provide any specific guidance as to how to predictably modify SEQ ID NO: 118, but adding, deleting, and substituting amino acids without altering the functional activity of the TRT protein. The specification at most teaches general screening methods in which one generate a large genus of polypeptides and screen these polypeptides for activity. However, screening all natural and non-natural variants of TRT, defined only as including a fragment having 60% identity with SEQ ID NO: 118 and including the broadly defined motifs of structures a)-f), is not considered routine in view of the significantly large number of proteins that would need to be made and tested. Such making and testing is constitutes nothing more than an invitation to experiment since the specification cannot be relied upon as providing sufficient guidance has to how to make and use specific TRT variants having telomerase catalytic activity when complexed with a telomerase RNA component.

In view of the breadth of the claims and the unpredictability in the art and lack of specific guidance provided in the specification, undue experimentation would be required to practice the invention as it is broadly claimed.

RESPONSE TO ARGUMENTS:

In the response of August 9, 2004 Applicants state that it is not the standard to require that the reader be able to identify all possible active variants, but only a reasonable number of variants without undue experimentation. It is asserted that since the specification teaches motifs, one would be able to determine which sequences outside of these motifs could be modified. Applicants assert that the claims "guide one of ordinary skill towards making alterations in the sequence regions that lie *outside the six motifs recited in the claims.*"

Applicants arguments have been fully considered but are not persuasive for the following reasons. Firstly, the teachings in the specification of conserved motifs does not provide sufficient guidance to enable the skilled artisan to determine how modification of any amino acid within the encoded protein will effect the activity of the protein. Applicants response appears to indicate that any amino acid outside of the conserved motifs can be modified without altering the biological properties of the encoded three-dimensional protein. However, Applicants have not provided evidence to support this contention. Non-conserved amino acids also effect the overall structure and function of the protein. No guidance has been provided as to how to modify e.g. 6 out of 10 of the "non-conserved" amino acids (over the full length of SEQ ID NO: 118 or fragments of SEQ ID NO: 118) without effecting telomerase catalytic activity. Following Applicants method as proposed in the amendment, one would use random mutagenesis to generate 20^{1132} potential variants of SEQ ID NO: 118, remove the members from this genus that do not contain the motifs specified in claim 119, and then assay this very

large genus of variants to determine which of the variants has telomerase catalytic activity. In view of the unpredictability in the overall structure-function relationship, such random experimentation is considered to be undue.

Applicants point to Example 14 of the Written Description Guidelines. Applicants discuss how this example states that a protein should be defined by its structure and functional activity and point out that the current claims go way beyond this. However, Applicants comments regarding written description do not apply to the present rejection because the present rejection is NOT a written description rejection and the statutes for written description and enablement and the criteria for meeting these statutes are not interchangeable. However, regarding structure, the claims very broadly define the structure of the protein encoded by the claimed polynucleotide. Again, the protein is defined as including motifs, having substantial variation in their sequences, and as containing 6 out 10 amino acids of some fragment of SEQ ID NO: 118 (e.g., 10 amino acids from within the conserved motifs). The structure of the proteins defined in the claims is not commensurate in scope with the proteins disclosed in the specification in that the specifcation deislcoses only one variant protein (which is excluded by the claims) and 7 TRT proteins from different species. As discussed above, the specification does not provide sufficient guidance as to how to reasonably identify additional polynucleotides encoding protein variants having telomerase catalytic activity. One of skill in the at would have to engage in excessive and undue experimentation in order to make and use the claimed genus of polynucleotides encoding TRT mutants, allelic variants, splice variants, and homologues.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 121-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 121 is indefinite over the recitation of "structure f) is joined to" SEQ ID NO: 477 because it is not clear as to whether SEQ ID NO: 477 may be attached at either terminus of structure f), whether additional amino acids may be inserted between structure f) and SEQ ID NO: 477, whether SEQ ID NO: 477 is attached directly or indirectly to structure f) and/or whether SEQ ID NO: 477 is joined to the protein by a linear or branched attachment.

Claims 121-125 are indefinite because it is unclear as to the relationship between SEQ ID NO: 473 and structure a), SEQ ID NO: 478 and structure b), SEQ ID NO: 370 and structure d) and SEQ ID NO 479 and structure e). The structures set forth in claims 121-125 include amino acids that are not present in the structures of claim 119 and/or omit amino acids that are present in the structures of 119. For example, claim 122 has been amended to recite that "structure a is h-Arg-h-X-Pro-Lys." However, the recited structure differs from the structure set forth in claim 119 in that it is missing 2 amino acids from one terminus and 3 amino acids from the other terminus (i.e., structure a) in claim 119 is: $\mathbf{X_3}$-Arg- X_2-Pro-Lys-$\mathbf{X_3}$. Accordingly, claims 121-125 do not further define the structures set forth in claim 119, but rather define structures that are distinct from those set forth in claim 119. Thereby, it is unclear as to what is intended to be the

relationship between the structures defined in claim 119 and the structures set forth in claims 121-125 and it is unclear as to how claims 121-125 are intended to be further limiting from claim 119.

Claim 126 is indefinite and confusing because it is unclear as to whether the protein contains 10 amino acids of SEQ ID NO: 118 in addition to the sequence comprising an amino acid sequence having 60% identity with SEQ ID NO: 118 or if claim 126 is intended to further define the "an amino acid sequence having 60% identity with SEQ ID NO: 118" such that this sequence consists of at least 10 amino acids of SEQ ID NO: 118.

RESPONSE TO ARGUMENTS:

In the response filed August 9, 2004, Applicants state that the claims have been amended to overcome the previous grounds of rejection under 35 U.S.C. 112, second paragraph. however, the claims as amended do not overcome the 112 second paragraph rejections for the reasons stated above.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 119-126 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 and 7-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '836 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '836. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '836 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 224 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 224 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '836 are encompassed by the presently claimed polynucleotides encoding any TRT.

RESPONSE TO ARGUMENTS:

In the response filed August 9, 2004, Applicants state that they will file a terminal disclaimer or take other appropriate action upon the indication of allowance of the claims. The rejection is maintained and made final for the reasons stated above.

6. Claims 119-126 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '809 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '809. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '809 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 1 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 1 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '809 are encompassed by the presently claimed polynucleotides encoding any TRT.

RESPONSE TO ARGUMENTS:

In the response filed August 9, 2004, Applicants state that the claim of '809 is directed to a polynucleotide encoding a Euplotes aedicaulatus TRT protein (SEQ ID NO: 1) having less than 60% identity with human TRT (SEQ ID NO: 118). Applicants state that the protein of SEQ ID NO: 1 in '809 shares only about 21% identity with the protein of present SEQ ID NO: 118. However, the present claims do not require that the polynucleotides encodes a protein having at least 60% identity over the full length of

SEQ ID NO: 118. Rather, the claims encompass polynucleotides which encode for a protein **that comprises an amino acid sequence at least 60% identical to SEQ ID NO: 118**. Thereby, the claims include polynucleotides encoding polypeptides which comprise fragments which share 60% identity with SEQ ID NO: 118. Since the protein of SEQ ID NO: 1 in '809 contains motifs a-f, this protein necessarily comprises a fragment having 60% identity with an amino acid sequence of SEQ ID NO: 118.

7. Claims 119-126 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,767,719. Although the conflicting claims are not identical, they are not patentably distinct from each other. The present claims are drawn broadly to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein that comprises a sequence having 60% identity with an amino acid sequence of SEQ ID NO: 118 (human TRT) and which comprises conserved motifs a-f as defined in claim 119. As broadly written, the present claims are inclusive of the polynucleotides claimed in '719 which encode for a protein having 90% identity with the mouse TRT sequence of SEQ ID NO: 2 and include the conserved motifs T, 1, 2 and A-D, as defined in '719. The protein of SEQ ID NO: 2 includes the motifs of a-f and comprises an amino acid sequence having at least 60% identity with a portion of SEQ ID NO: 118. Accordingly, the polynucleotides claimed in '719 anticipate the claimed polynucleotides encoding a TRT.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 119-126 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,093,809).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is

no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding Euplotes aediculatus, Schizosaccharomyces, Saccharomyces and human telomerase. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

10. Claims 119-126 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,309,867).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding Euplotes aediculatus, Schizosaccharomyces, Saccharomyces and human telomerase. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

RESPONSE TO ARGUMENTS:

In the response filed August 9, 2004, Applicants traversed each of the above 102(e) rejections by stating that the cited art is not prior art to the claimed invention. Applicants state that the present application claims priority to 08/724,643, filed October 1, 1996 and that each of the cited references has a later publication or filing date. However, a statement of priority to an earlier application does not necessarily entitle one to this priority. The '643 application does not provide basis for each of the limitations set forth in claims 119-126. Applicants have not pointed to any particular teachings in the '643 application which provide specific basis for the genus of polynucleotides set forth in the present claims. Applicants argue that if the '809 and '867 patents are not considered to be enabling, then they may not be considered as prior art. But if the cited patents are enabling, then they would not constitute prior art. Applicants states that the patent office cannot have it both ways. However, neither may applicant. The cited art is enabling to the same degree that the present invention is enabled. Applicants response does not clarify why the prior art is or is not enabling or why the presently claimed invention is distinguisable over the prior art. Further, the '836 and '809

patents are enabling for the specific nucleic acids set forth therein which comprise the motifs of SEQ ID NO: 16/17, 139, 143, 144, 146 and 147. Applicants were not given priority to the '809 and '836 patents because these patents do not provide support for the presently claimed invention. It is notd that a claim as a whole is given a date of priorit, rather than the individual components of the claim. The '809 and '836 patents do not provide basis for the concept of the presently claimed genus of any nucleic acid encoding a protein having 60% with an amino acid sequence of SEQ ID NO: 118 and comprise the sequences of SEQ ID NO: 16/17, 139, 143, 144, 146 and 147.

11. Claim 119 is rejected under 35 U.S.C. 102(a) as being anticipated by Linger et al (Gen Bank Accession No.U95964).

Linger teaches an isolated polynucleotide encoding the p123 telomerase subunit of Euplotes aediculatus. The protein encoded by the polynucleotide of Linger contains the motifs set forth in present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147.

12. Claim 119 is rejected under 35 U.S.C. 102(a) as being anticipated by Lendvay (Genetics (Dec 1996) 144: 1399-1412: cited in the IDS).

Lendvay teaches an isolated polynucleotide EST2 gene encoding the telomerase subunit of Saccharomyces cerevisiae. The protein encoded by the polynucleotide of Linger contains the motifs set forth in present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147.

RESPONSE TO ARGUMENTS:

In the response filed August 9, 2004, Applicants traversed each of the above 102(a) rejections by stating that the office has not shown that the references teach

nucleic acids which have at least 60% identity to the claimed polynucleotides. However, the claims do not require nucleic acids which encode for proteins having 60% identity over the full length of SEQ ID NO: 118. Rather the claims require nucleic acids comprising "an amino acid sequence" (i.e., any fragment/length of amino acids) having at least 60% identity with SEQ ID NO: 118. Since the nucleic acids of Linger and Lendvay contain each of the recited motifs, these nucleic acids necessarily share at least 60% identity with "an amino acid sequence" of SEQ ID NO: 118 .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Carla Myers
December 22, 2004

CARLA J. MYERS
PRIMARY EXAMINER